REMARKS

Claims 1-22 are pending in the application. Applicants have amended claim 17 to overcome the improper dependency. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attachment is captioned "Version with markings to show changes made."

The Rejections Under 35 U.S.C. §103

The Examiner had rejected claims 1-8 and 9-22 as being obvious over U.S. Patent Nos. 5,462,746 ("Wolter '746") or 6,217,904 ("Midha '904"). Applicants hereby request reconsideration and withdrawal of these rejections in view of the following arguments.

The Examiner asserted that it would have been obvious to one ordinarily skilled in the art at the time the invention was made to modify the composition of Wolter '746 or Midha '904 to contain one isomer of amphetaminil (and by extension any other isomer of a racemic compound) over another because such isomers are expected to have differing activities e.g. physiological. The Examiner went on to cite In re Anthony 162 USPQ 594 and In re Adamson 125 USPQ 233 for the proposition that optically active isomer substitution is obvious.

Applicants contend that the Examiner has erred in applying these cases to reject the claims of the application for obviousness. As In re Anthony makes clear (page 596 citing In re Adamson and Brenner et al. v. Ladd (147 USPQ 87)), a stereoisomer is not patentable over its known racemic mixture *unless* it possessed unexpected properties not possessed by the racemic mixture.

The exception just outlined is exactly the case of Applicants' invention. As Applicants specifically make clear:

- page 4, lines 5-9: Less stereotypic behavior is elicited by this compound than by racemic amphetaminil;
- page 7, lines 4-15: Improved and unexpected pharmacologic and dose responsive effects are obtained over those of the racemic compound by using only an active form of amphetaminil.
- page 1, lines 20-25: These improved activities were previously unknown as the heretofore commercially available form of amphetaminil being a racemate. Amphetaminil that is substantially enantiomerically pure at the first dissymmetric center had not been previously prepared or evaluated for pharmacological activity.
- page 33, lines 7-15: (R,R'), (R, S')-amphetaminil ("pure R amphetaminil") showed a higher ratio of Locomotor response to Stereotypy response that did racemic amphetaminil suggesting that "pure R amphetaminil" would be less likely to elicit or exacerbate movement disorders in patients and may thus possess previously unknown benefits in the treatment of ADHD patients, 12% of whom manifest motor tics.

The foregoing arguments clearly demonstrate that in fact, Applicants invention is an enantiomer that possesses unexpected properties. Because the beneficial effects were unexpected, it would not have been obvious for one of ordinary skill at the time of the invention to isolate pure R amphetaminil and thus it would not have been obvious to

modify the composition in either of the cited references using the isolated isomer. Nor, as the Examiner asserted in rejecting claims 9-22, would it have been obvious to use the isolated isomer in the method of Midha '904, with or without the teaching of Wolter '746. The Examiner's arguments regarding modification of the dosage, amount, and use of pharmaceutically acceptable salts of the isolated isomer cannot stand for the same reason since the isolation and use of the isomer would not have been obvious. Applicants accordingly request withdrawal of the rejections and reconsideration of claims 1-8 and 9-22.

No additional fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

Respectfully submitted,

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Date: August 26, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Seth Lederman et al.

SERIAL NO. : 09/992,235 EXAMINER: Delacroix Muirhei, Cybille

FILED : November 6, 2001 ART UNIT: 1614

FOR : (R,R'), (R, S') AMPHETAMINIL COMPOSITIONS AND USES THEREOF

VERSION WITH MARKINGS TO SHOW CHANGES MADE

17. (Amended) The method of claim 15 wherein the amount of (R,R'), (R, S')-amphetaminil sulfate or another pharmaceutically acceptable salt thereof is greater than about 90% of the weight of the total amphetaminil.